REMARKS

Status of the Claims

Claims 1-4, 6-11, 13-18, 20-23, 25, 26 and 28-32 are pending in this application. Claims 5, 12, 19, 24 and 27 have been canceled. Claims 28-32 have been added. Claim 28 does not add new matter because it has support in the specification at page 4, lines 14-16 and page 5, lines 23-27. The new claims also do not raise any new issues for consideration. Claims 1, 2, 8, 22 and 25 have been amended to include the addition of a filler that is not wax to the medicinal composition. Support is found at page 6 of the specification. As such, Applicants respectfully request entry of the present amendment.

Rejections Under 35 U.S.C. § 102(b)

The Examiner rejects claims 1-3, 6-10, 13-17 and 20-22 as anticipated by Aoki et al. (JP Publication Number 07267850 A; hereinafter "Aoki"). Applicants traverse the rejection and respectfully request the withdrawal thereof.

The present invention is directed to a medicinal composition not having an unpleasant taste comprising a medicine having an unpleasant taste, an anionic polymer and having additional fillers (which are not wax). The unpleasant taste of the medicine is masked by the anionic polymer interacting with the positive charge of the medicine.

As a result of the interaction, the medicine does not separate from the polymer when introduced to saliva or water. The fillers in the medicinal composition may be starch, lactose, mannitol, etc. However, the filler is not intended to encompass wax.

Aoki is discussed at page 1, lines 11-14 of the specification under the heading "Prior Art". Aoki discloses a mixture of a medicine having an unpleasant taste with a water soluble polymer and wax. The composition is fused by melting the wax so that the medicine and water soluble polymer are sealed in the matrix of the fused wax.

Aoki fails to disclose the interaction of the basic medicine with an anionic polymer. Moreover, Aoki discloses a composition that has wax as an essential ingredient. The wax in Aoki is used to encapsulate the unpleasant tasting medicine.

The present invention is distinguished from Aoki in that the present invention does not use wax. Instead the present invention uses an anionic polymer to mask the unpleasant taste of the medicine. The polymer surrounds the medicine and prevents the medicine from being released in the presence of water or saliva. Furthermore, at page 1 of the specification, Applicants recognize and distinguish the wax method of masking an unpleasant tasting medicine. Aoki is cited under the heading of "Prior Art". As such, Applicants submit that the

present invention is distinguished from Aoki and patentable over Aoki. Thus, the rejection should be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

1. Aoki in view of Matoba '612

The Examiner rejects claims 4, 11, 18, 23 and 26 as obvious over Aoki in view of Matoba et al. (U.S. Patent 5,464,612; hereinafter Matoba '612). Applicants traverse the rejection and respectfully request the withdrawal thereof.

Matoba '612 discloses a clad powdery or granular preparation of a medicinally active ingredient having a bitter taste, such as antibiotics, antihistamines and antimicrobial agents. The medicines may be contained in the clad powdery or granular preparation.

Applicants rely on the arguments stated above regarding Aoki. Aoki is distinguished from the present invention in that Aoki employs a wax for masking the unpleasant taste of the medicine, whereas in the present invention, an anionic polymer is combined with the basic medicine, and the combination is such that water and saliva do not cause the release of the unpleasant tasting medicine.

The primary reference fails to disclose the elements of the present invention. The additional disclosure of Matoba '612 fails to add the necessary disclosure to motivate one of ordinary skill in the

art to arrive at the present invention of a medicinal composition made up of a basic medicine, an anionic polymer and filler, where the filler is other than wax. As such, Applicants respectfully request that the rejection be withdrawn.

2. Aoki in view of the Vantin® Article

The Examiner has rejected claims 5, 12, 19, 24 and 27 under 35 U.S.C. § 103(a) over Aoki in view of the Internet article of drug information on "Vantin® (Pharmacia & Upjohn)" (article obtained through on-line PDR) (hereinafter "Vantin®"). Applicants traverse the rejection and respectfully request the withdrawal thereof.

Applicants submit that there is no proof that the Internet Vantin® reference was available at the time of filing the present application or was available before Applicants' priority date. At best, the cited Internet article was downloaded in the year 2002, and has a "2002 Copyright" date. Thus, Vantin® is not considered a prior art reference. *See* M.P.E.P. § 2128 ("Date of Availability" section, where no publication date of an Internet articles means the article cannot be relied upon as prior art). In addition, there is no proof that this article represents the state of the art when the present invention was made.

Assuming *arguendo* that the reference was publicly available prior to the filing date of the present application, the combination of the internet reference and Aoki still fails to motivate one of

ordinary skill in the art to make the present invention, because all of the elements of the present invention are not disclosed or suggested. Aoki fails as a primary reference for the reasons stated above.

Moreover, Applicants submit that the cited Internet article cannot be combined with Aoki because there is no motivation in the cited Vantin® article for such a combination. The disclosure in Vantin® does not provide the requisite motivation that Aoki would need to make a *prima facie* case of obviousness. While the reference need not expressly teach that the disclosure contained therein should be combined with another, *see Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997), the showing of combining references "must be clear and particular". *See also In re Dembiczak*, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Applicants submit that nothing in the Vantin® reference suggests or discloses such a combination. In other words, the Vantin® reference is merely used to account for the lack of disclosure present in Aoki, without any basis for combining these references. Thus, any usage of the Vantin® article is nothing short of improper hindsight reconstruction.

Thus, the Vantin® reference and Aoki cannot be properly combined so as to disclose or suggest all the elements of claims 5, 12, 19, 24 and 27. Vantin® cannot even be used in combination with Aoki because it does not antedate the filing date or the priority date of the

present application. As such, Applicants respectfully request that the rejection be withdrawn.

Conclusion

As Applicants have addressed and overcome all rejections in the Office Action, Applicants respectfully request that the rejections be withdrawn and that the claims be allowed.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. § 1.17 and 1.136(a), Applicants respectfully petition for a three (3) month extension of time for filing a response in connection with the present application. The required fee of $920.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims have been amended as follows:

1. (Amended) An oral medicine composition preventing an unpleasant taste which comprises a basic medicine having [the] an unpleasant [taste and] taste, an anionic [polymer.] polymer, and a filler.

2. (Amended) The medicine composition according to Claim 1 wherein the anionic polymer is at least one selected from the group consisting of carrageenan, chondroitin sulfate, dextran sulfate, alginic acid, gerun gum, xanthan gum and salts [thereof.] thereof and the filler is other than wax.

8. (Amended) A method for preventing an unpleasant taste which comprises the step of blending an anionic polymer with a basic medicine having an unpleasant [taste] taste and a filler.

22. (Amended) An oral medicine preventing an unpleasant taste which comprises a basic medicine having [the] an unpleasant [taste] taste, a filler and an anionic polymer,

wherein said anionic polymer is at least one selected from the group consisting of carrageenan, chondroitin sulfate, dextran

sulfate, alginic acid, gerun gum, xanthan gum and salts [thereof, and] thereof;

said anionic polymer is in an amount of 0.1 to 20 parts by weight with respect to 1 part by weight of the basic substance having the unpleasant [taste.] taste; and

said filler is other than wax.

25. (Amended) A method for preventing an unpleasant taste which comprises the step of blending an anionic polymer with a basic medicine having an unpleasant [taste,] taste and a filler,

wherein said anionic polymer is at least one selected from the group consisting of carrageenan, chondroitin sulfate, dextran sulfate, alginic acid, gerun gum, xanthan gum and salts [thereof, and] thereof;

said anionic polymer is in an amount of 0.1 to 20 parts by weight with respect to 1 part by weight of the basic substance having the unpleasant taste; and

said filler is other than wax.

Claims 28-32 have been added.